Summary of Safety and Effectiveness
Smith & Nephew, Inc. Gender Knee Systems

Contact Person and Address
Jason Sells
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Smith & Nephew, Inc.
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Memphis, Tennessee 38116
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Date of Summary: August 16, 2007

AUG 17 2007

Name of Device: Smith & Nephew, Inc. Gender Knee Systems
Common Name: Total Knee Prosthesis
Device Classification: 21 CFR 888.3560 (Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis – Class II); and 21 CFR 888.3565 (Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis – Class II)

Device Description
The Smith & Nephew, Inc. Gender Knee Systems are the existing Smith & Nephew, Inc. Genesis II, Legion, and Journey BCS Knee Systems. This premarket notification seeks only to add gender-related claims for these existing total knee systems previously cleared by FDA marketed by Smith & Nephew. No new total knee components being introduced as a result of this premarket notification.

Intended Use
Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result; failed osteotomies, unicompartmental replacement, or total knee replacement. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are absent or incompetent and the collateral ligaments remain intact. Constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent. Total knee components are single use devices and may be used in cemented or uncemented applications.

Substantial Equivalence Information
The Smith & Nephew, Inc. Gender Knee Systems are the existing Smith & Nephew, Inc. Genesis II, Legion, and Journey BCS Knee Systems previously cleared for market by FDA through various premarket notifications. The gender-specific claims being made about these devices are similar to those of the Zimmer NexGen Knee Gender Solutions Female (GSF) Femoral Components (K060370), the Zimmer Gender Solutions Natural-Knee Flex System (K070214), and the Stryker Triathlon Total Knee System (K053514).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
% Mr. Jason Sells
Project Manager, Regulatory Affairs
1450 Brooks Road
Memphis, Tennessee 38116

AUG 17 2007

Re: K071790
Trade/Device Name: Gender Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: June 29, 2007
Received: July 2, 2007

Dear Mr. Sells:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071790

Device Name: Smith & Nephew, Inc. Gender Knee Systems

Indications for Use:

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Prescription Use	X	AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucchi

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071790